REMARKS

In the Office Action dated November 28, 2008, the drawing amendment and the specification amendment that were made in Applicants' previous response were objected to as introducing new matter into the specification, because the Examiner stated Figure 1 as originally filed shows the dosing tube 22 proceeding through the tracheal tube 4, and the Examiner stated this is consistent with the statement at page 7 in the application as originally filed that proteins are administered "via a dosing tube 22 to the patient's trachea and further down to the lungs." Applicants acknowledge that this statement is consistent with the showing of the dosing tube 22 in Figure 1 as originally filed, but also believe it is consistent with the dosing tube being configured as shown in the amended drawing. In any event, another amended drawing is submitted herewith wherein the original positioning of line 22 has been retained, and an additional line 22a has been indicated. The line 22a is supported in the specification as originally filed by original claim 4 (the claims being a part of the specification), which clearly defines a flow path for the fluid that includes the pumping device and the first and second tubes, and further describes a dosing unit in fluid communication with that flowpath for administering a dose of a medicament into the fluid. This is now clearly shown by the tube 22a in amended Figure 1. Figure 1 has therefore simply been amended to conform to the claims as originally filed and no new matter is added thereby.

The actual amendment to the written portion of the specification made in Applicants' previous response made no mention of the tube 22, and only referred to the membrane 6A. It is therefore not clear why the amendment to the specification was objected to as an attempt to introduce new matter. Nevertheless, Applicants

submit that the present amendment to Figure 1 and the amendment to the specification are fully supported by the specification as originally filed.

Claims 1, 3-5 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over, Kruse et al.

This rejection is again respectfully traversed for the following reasons.

In Applicants' previous response, Applicants argued that the first and second tubes in the present invention are located outside of the tracheal tube and outside of the cuff, but the Examiner noted that such a limitation was not present in independent claim 1, and the Examiner also stated there is no support in the specification for such a limitation, since no structural relationship can be ascertained from Figure 1 of the present application.

Although Figure 1 is clearly intended to be a schematic illustration, Applicants nevertheless submit that a person of ordinary skill can easily discern basic structural relationships from Figure 1. For example, the tube 22 is clearly shown as proceeding inside and through the tracheal tube 4, and the cuff 6 is shown outside of the tracheal tube, and of course the cuff 6 cannot possibly be placed inside the tracheal tube, since that would destroy its intended operation of being in contact with the trachea. This being the case, since the first and second tubes 8 and 10 are clearly shown as being connected at the exterior of the cuff 6, this means they must also be outside of the tracheal tube 4. A person of ordinary skill in the field of designing respiratory-assist devices would clearly understand that the tubes 8 and 10 could not possibly be connected to the cuff 6 and simultaneously be at any location except outside of the tracheal tube 4.

Since the tubes in the Kruse et al. reference that the Examiner contends correspond to the tubes 8 and 10 are clearly inside the tube that the Examiner contends corresponds to the tracheal tube in claim 1, this added limitation in claim 1, by itself, is sufficient to overcome the anticipation rejection of claim 1 based on Kruse et al.

The obviousness rejection of claim 1 based on Kruse et al. is also respectfully traversed, for the following reasons.

Applicants continue to submit that the tube disclosed in the Kruse et al. reference is not a tracheal tube, and cannot be used as a tracheal tube, and would not be "interpreted" by a person of ordinary skill in the field of respiratory-assist devices as being a tracheal tube or being capable of use as a tracheal tube.

In response to extensive details supporting this argument that were presented in Applicants' previous response, the Examiner in the November 28, 2008 Office Action stated that there is no limit to the number of locations within the body that the device disclosed in the Kruse et al. reference can be used, and the Examiner also noted the passage at column 6, lines 14-17 in the Kruse et al. reference stating that the distal orifices 32 are provided to obviate occlusion of all safety pressure relief lumen orifices by contact with tissue during a procedure such as aspiration. If the Examiner by this statement is somehow equating "aspiration" with "respiration," Applicants respectfully submit the Examiner is mistaken. The attached definition of "aspiration" from an online dictionary provides the standard definition for that term, and it clearly does not mean the same as "respiration." This is also consistent with the passage in the Kruse et al. reference immediately following the passage noted by the Examiner at column 6, lines 20-29, which states that the proximal end of the

lumen 24 can be connected to a suction pump 4 aspirating liquid or gas from an organ or tissue as a diagnostic or therapeutic maneuver, or connection to a syringe, infusion pump or other delivery system for introducing drugs or liquid nutrients into a tissue or organ.

Moreover, in order for the tube disclosed in the Kruse et al. reference to be modified to conform to the current claim language, this would mean that, for no reason at all, the interior tubes therein, which the Examiner contends correspond to the first and second tubes in claim 1 of the present application, would have to be moved outside of the lumen 24, thereby making it even less suitable for insertion in the trachea, in the context of the device disclosed in the Kruse et al. reference. Moreover, if this were done (again for no practical reason whatsoever that is discernable from the Kruse et al. disclosure), those tubes would then have to be reintroduced into the interior of the lumen 24 so as to communicate with the component that the Examiner considers to correspond with the cuff in claim 1 of the present application.

By contrast, in the subject matter disclosed and claimed in the present application, all of these connections are meaningful and reasonable, because the cuff, as is usual, is located outside of the tracheal tube and therefore is easily accessible by the aforementioned first and second tubes. Modifying the Kruse et al. reference in such a manner (again, for no discernable practical reason disclosed in the Kruse et al. reference) would be a substantial redesign of that lumen, rather than a simple modification, and therefore would be well beyond any type of allegedly obvious modification within the scope of 35 U.S.C. §103(a).

Claim 1, therefore, is not anticipated by the Kruse et al. reference nor would claim 1 have been obvious to a person of ordinary skill in the field of designing respiratory-assist devices, under the provisions of 35 U.S.C. §103(a), based on the disclosure of Kruse et al.. The same is true with regard to claims 3-5 and 8 depending from claim 1.

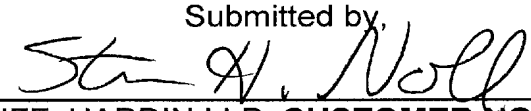
Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al. in view of Schultze, and claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al. in view of Hanson et al., and further in view of Walther et al.

The above arguments with regard to claim 1 are equally applicable to these rejections. Even if the Examiner's statements concerning these secondary references are correct, modifying the Kruse et al. reference in view of the teachings of those secondary references still would not result in the subject matter of either claims 6 or 7, for the reasons discussed above in connection with independent claim 1.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



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